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TITLE: Self-destructing, controlled release peroral drug delivery system

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INVENTOR-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY
Ritschel; Wolfgang A.	Cincinnati	OH		
Agrawal; Mukul A.	Strongsville	OH		

US-CL-CURRENT: 424/473; 424/464, 424/465, 424/466, 424/468, 424/469, 424/470, 424/471, 424/472

CLAIMS:

What is claimed:

1. An oral tablet for delivering a beneficial agent to a mammal, comprising:

a core compartment having a beneficial agent; and

a unitary self-destructing shell surrounding the core compartment, the self-destructing shell comprising a plurality of disintegrant particles dispersed within a semipermeable matrix.

2. The tablet of claim 1 wherein the core compartment further comprises means for delivering the beneficial agent from the tablet.

3. The tablet of claim 1 wherein the self-destructing shell comprises at least one disintegrant within a matrix.

4. The tablet of claim 3 wherein the disintegrant comprises a core surrounded by a disintegrant delay jacket, the core including a swelling agent.

5. The tablet of claim 4 wherein the swelling agent is selected from the group consisting of an insoluble

polysaccharide, a hydrogel, a swellable, hydrophilic polymer, a water insoluble copolymer of maleic anhydride, a water swellable polymer of an N-vinyl lactam, a polymer which forms a hydrogel upon contact with an imbibed fluid, and combinations thereof.

6. The tablet of claim 5 wherein the insoluble polysaccharide is selected from the group consisting of starch, cellulose, and combinations thereof.

7. The tablet of claim 5 wherein the hydrogel is selected from the group consisting of polyethylene glycol, hydroxypropyl methylcellulose, hydroxyethyl cellulose, and combinations thereof.

8. The tablet of claim 5 wherein the swellable, hydrophilic polymer is selected from the group consisting of poly(hydroxyalkylmethacrylate, poly(vinylpyrrolidone, polyelectrolyte complexes, poly(vinyl alcohol, methyl cellulose, cross-linked agar, carboxymethyl cellulose, and combinations thereof.

9. The tablet of claim 5 wherein the water insoluble copolymer of maleic anhydride includes a monomer selected from the group consisting of styrene, ethylene, propylene, butylene, isobutylene, and combinations thereof.

10. The tablet of claim 5 wherein the polymer which forms a hydrogel upon contact with an imbibed fluid is selected from the group consisting of an acidic carboxy polymer, a metal salt of an acidic carboxy polymer, a polyacrylamide, a cross-linked, water-swellable, indine-maleic anhydride polymer, a polyacrylic acid, a metal salt of a polyacrylic acid, a polyethylene oxide polymer, a starch graft copolymer, an acrylate polymer; a diester cross-linked polyglucan, and combinations thereof.

11. The tablet of claim 4 wherein the disintegrant delay jacket comprises a component selected from the group consisting of a binder, an osmotic agent, a tablet lubricant, and combinations thereof.

12. The tablet of claim 3 wherein the matrix includes a material selected from the group consisting of cellulose

acetate, ethylcellulose, a polymethacrylic acid ester, an acrylic acid ester/methacrylic acid copolymer with at least one quarternary ammonium group, cellulose triacetate, agar acetate, amylose triacetate, beta glucan acetate, beta glucan triacetate, cellulose acetate ethyl carbamate, cellulose acetate phthalate, cellulose acetate methyl carbamate, cellulose acetate succinate, cellulose acetate dimethylaminoacetate, cellulose acetate ethyl carbonate, cellulose acetate methyl sulfonate, cellulose acetate butyl sulfonate, a cellulose ether, cellulose acetate propionate, a polyvinyl methyl ether polymer, cellulose acetate laurate, methyl cellulose, cellulose acetate p-toluene sulfonate, triacetate of locust bean gum, cellulose acetate with acetylated hydroxyethyl cellulose, hydroxylated ethylenevinylacetate, a polymeric epoxide, an alkylene oxide-alkyl glycidyl ether, a polyurethane, polyglycolic acid, and combinations thereof.

13. The tablet of claim 3 wherein the matrix includes a material selected from the group consisting of cellulose acetate, ethylcellulose, a polymethacrylic acid ester, an acrylic acid ester/methacrylic acid copolymer with at least one quarternary ammonium group, and combinations thereof.

14. The tablet of claim 1 wherein the self-destructing shell comprises at least one aqueously dispersible, pharmaceutically acceptable, polymeric compound.

15. The tablet of claim 14 wherein the aqueously dispersible, pharmaceutically acceptable, polymeric compound is selected from the group consisting of a methacrylic ester copolymer, poly(ethyl acrylate, methyl methacrylate), poly(ethyl acrylate, methyl methacrylate, trimethylammonioethyl methacrylate chloride), a polymethyl methacrylate-methacrylic acid copolymer, cellulose acetate, ethylcellulose, cellulose acetate phthalate, hydroxypropyl methylcellulose phthalate, and combinations thereof.

16. The tablet of claim 1 wherein the beneficial agent formulation further includes an additional agent, the additional agent selected from the group consisting of an osmotic agent, a lubricant, a glidant, a wetting agent, a viscosity-modulating vehicle, a surfactant, a binder, a

filler, a suspending agent, a thickening agent, a pharmaceutically acceptable carrier, and combinations thereof.

17. The tablet of claim 1 wherein the beneficial agent formulation comprises from about 5 nanograms to about 20 grams of the first beneficial agent.

18. The tablet of claim 1 wherein the first beneficial agent is selected from the group consisting of a protein, a peptide, an antiasthmatic, an antianginal, a corticosteroid, a 5-lipoxygenase inhibitor, an antihypertensive, a leukotriene B4 receptor antagonist, and combinations thereof.

19. The tablet of claim 1 wherein the first beneficial agent is selected from the group consisting of theophylline, IGF-1, PTH (1-34), TGF alpha, TGF beta 1, TGF beta 2, TGF beta 3, IFN alpha, hybrid IFN alpha, IFN gamma, hirudin, heparin, calcitonin, 5-aminosalicylic acid,
N-hydroxy-N-((6-phenoxy-2H-1-benzopyran-3-yl)methyl)-urea,
4-[5-[4-(aminoiminomethyl)phenoxy]pentoxy]-3-methoxy-N
,N-bis(1-methylethyl)benzamide (Z)-2-butenedioate,
N-[2-[[2-[[4-(4-fluorophenyl)phenyl]methyl]-1,2,3,4-tetrah
quinolinyl]oxy]ethyl]-N-hydroxyurea,
1-(1-benzo[b]thien-2-ylethyl)-1-hydroxyurea,
5-[2-(2-carboxyethyl)-3-[6-(para-methoxyphenyl)-5E-hexenyl
ric acid, beclomethasone dipropionate,
betamethasone-17-valerate, prednisolone
metasulfobenzoate, tixocortol pivalate, budesonide,
fluticasone, metoprolol, a pharmaceutically acceptable salt thereof, and combinations thereof.

20. The tablet of claim 1 wherein the core compartment further comprises an osmotic agent.

21. The tablet of claim 1 wherein the core compartment further comprises an excipient selected from the group consisting of a binder, a hygroscopic suspending agent, a hygroscopic thickening agent, a tablet lubricant, and combinations thereof.

22. The tablet of claim 1 further including a second beneficial agent, the second beneficial agent positioned exterior to the self-destructing shell.

23. The tablet of claim 22 further comprising an enteric coating.

24. The tablet of claim 23 wherein the enteric coating is selected from the group consisting of cellulose acetate phthalate NF, hydroxypropyl methylcellulose phthalate NF, polyvinyl acetate phthalate NF, methacrylic acid copolymer NF, and combinations thereof.

25. The tablet of claim 23 wherein the second beneficial agent is positioned between the self-destructing shell and the enteric coating.

26. The tablet of claim 23 wherein the enteric coating is positioned between the self-destructing shell and the second beneficial agent.

27. The tablet of claim 2 wherein the self-destructing shell further comprises an exit means.

28. The tablet of claim 27 wherein the exit means includes a release orifice.

29. The tablet of claim 28 wherein the release orifice has a cross-sectional diameter between about 0.05 mm and about 1.5 mm.

30. The tablet of claim 2 wherein the means for delivering the beneficial agent formulation from the delivery system includes a push means.

31. The tablet of claim 30 wherein the push means includes an osmopolymer.

32. The tablet of claim 31 wherein the osmopolymer is selected from the group consisting of an insoluble polysaccharide, a hydrogel, a swellable, hydrophilic polymer, a water insoluble copolymer of maleic anhydride, a water swellable polymer of an N-vinyl lactam, a polymer which forms a hydrogel upon contact with an imbibed fluid, and combinations thereof.

33. The tablet of claim 32 wherein the insoluble polysaccharide is selected from the group consisting of starch, cellulose, and combinations thereof.

34. The tablet of claim 32 wherein the hydrogel is selected from the group consisting of polyethylene glycol, hydroxypropyl methylcellulose, hydroxyethyl cellulose, and combinations thereof.

35. The tablet of claim 32 wherein the swellable, hydrophilic polymer is selected from the group consisting of poly(hydroxyalkylmethacrylate, poly(vinylpyrrolidone, polyelectrolyte complexes, poly(vinyl alcohol, methyl cellulose, cross-linked agar, carboxymethyl cellulose, and combinations thereof.

36. The tablet of claim 32 wherein the water insoluble copolymer of maleic anhydride includes a monomer selected from the group consisting of styrene, ethylene, propylene, butylene, isobutylene, and combinations thereof.

37. The tablet of claim 32 wherein the polymer which forms a hydrogel upon contact with an imbibed fluid is selected from the group consisting of an acidic carboxy polymer, a metal salt of an acidic carboxy polymer, a polyacrylamide, a cross-linked, water-swellable, indine-maleic anhydride polymer, a polyacrylic acid, a metal salt of a polyacrylic acid, a polyethylene oxide polymer, a starch graft copolymer, an acrylate polymer; a diester cross-linked polyglucan, and combinations thereof.

38. The tablet of claim 31 wherein a diaphragm is interposed between the osmopolymer and the beneficial agent formulation.

39. The tablet of claim 31 wherein the push means further comprises an osmagent.

40. The tablet of claim 39 wherein the osmagent is selected from the group consisting of an inorganic salt, a salt of an organic acid, an organic acid, a carbohydrate, a water-soluble amino acid, magnesium sulfate, magnesium carbonate, urea, saccharin, sodium saccharin, glycerin, hexylene glycol, polyethylene glycol, propylene glycol, and combinations thereof.

41. The tablet of claim 40 wherein the inorganic salt is

selected from the group consisting of sodium chloride, potassium chloride, magnesium chloride, sodium hydrogen phosphate, potassium hydrogen phosphate, dihydrogen phosphate, and combinations thereof.

42. The tablet of claim 40 wherein the salt of the organic acid is selected from the group consisting of sodium alginate, sodium ascorbate, sodium benzoate, sodium citrate, edetate disodium, sodium fumarate, sodium acetate, potassium acetate, magnesium succinate, and combinations thereof.

43. The tablet of claim 40 wherein the organic acid is selected from the group consisting of alginic acid, ascorbic acid, citric acid, edetic acid, malic acid, sorbic acid, and combinations thereof.

44. The tablet of claim 40 wherein the carbohydrate is selected from the group consisiting of a dextrate, sorbitol, xylitol, maltitol, mannitol, arabinose, ribose, xylose, glucose, dextrose, fructose, galactose, mannose, sucrose, maltose, lactose, raffinose, and combinations thereof.

45. The tablet of claim 40 wherein the water-soluble amino acid is selected from the group consisting of glycine, leucine, alanine, methionine, and combinations thereof.

46. A method of delivering a beneficial agent to a mammal in need thereof, comprising the step of orally administering the tablet of claim 1 to the mammal.

47. A method of delivering a colonically-active or colonically-absorable beneficial agent to the colon of a mammal in need thereof, comprising the step of orally administering the tablet of claim 1 to the mammal.

48. A method of delivering a beneficial agent to a mammal in need thereof, comprising the step of orally administering the tablet of claim 2 to the mammal.

49. A method of delivering a beneficial agent to the lower portion of the small intestine of a mammal in need thereof, comprising the step of orally administering the tablet of claim 3 to the mammal.

50. A method of delivering a beneficial agent to the lower portion of the small intestine of a mammal in need thereof, comprising the step of orally administering the tablet of claim 15 to the mammal.

51. A method of delivering a beneficial agent to the lower portion of the small intestine of a mammal in need thereof, comprising the step of orally administering the tablet of claim 31 to the mammal.

52. A method of making an oral tablet for delivering a beneficial agent to a mammal, comprising the steps of:

forming a core compartment having a beneficial agent; and

surrounding the core compartment with a unitary self-destructing shell, the self-destructing shell comprising a plurality of disintegrant particles dispersed within a semipermeable matrix.

53. The method of claim 52 wherein each of the disintegrant particles comprises a core and a disintegrant delay jacket, the core including a swelling agent, and the disintegrant delay jacket surrounding the core.

54. The method of making an oral tablet for delivering a beneficial agent to a mammal, comprising the steps of:

forming a core compartment including a first end wall, an oppositely disposed second end wall, a sidewall between the first and second end walls, a diaphragm having a first side and a second side, a beneficial agent positioned on one of the first and second sides, and a push means positioned on the other one of first and second sides, the diaphragm constructed and arranged to be slideble within the core compartment; and

surrounding the core compartment with a unitary shell.

55. The method of claim 54 further including the step of positioning an external delay jacket exterior to the unitary shell.

56. The method of claim 54 wherein the unitary shell

comprises a self-destructing shell having a plurality of disintegrant particles dispersed within a semi-permeable matrix.

57. The method of claim 56 further including the step of positioning an enteric coating exterior to the self-destructing shell.

58. The method of claim 57 further including the step of positioning a second beneficial agent exterior to the core compartment.

59. The method of claim 58 wherein the second beneficial agent is positioned between the self-destructing shell and the enteric coating.

60. The method of claim 58 wherein the second beneficial agent is positioned exterior to the enteric coating.

61. The method of claim 54 wherein the unitary shell is semi-permeable and includes an exit means.

62. The method of claim 54 wherein the push means includes an osmopolymer.

63. The method of claim 62 wherein the osmopolymer includes a dry hydrogel-forming powder.

64. The method of claim 58 further including the step of positioning an external delay jacket exterior to the self-destructing shell, the external delay jacket being water-soluble, permeable to the first and second beneficial agents, and comprising a component selected from the group consisting of a binder, an osmotic agent, a lubricant, and combinations thereof.

65. The oral tablet of claim 1 wherein the self-destructing shell is constructed and arranged to begin to erode by the time the oral tablet reaches the environment of use.

66. The oral tablet of claim 1 wherein the self-destructing shell is constructed and arranged to begin to erode before the oral tablet reaches the environment of use.

67. An oral tablet for delivering a beneficial agent to a mammal, comprising:

a core compartment; and

a unitary shell surrounding the core compartment,

the core compartment including a first end wall, an oppositely disposed second end wall, and a sidewall between the first and second end walls,

the core compartment further including a diaphragm having a first side and a second side, a beneficial agent positioned on one of the first and second sides, and a push means positioned on the other one of the first and second sides, the diaphragm constructed and arranged to be slideable within the core compartment.

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